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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/040,842

01/07/2002

Ulrich Posanski

4-20017D

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1095

7590

01/15/2003

THOMAS HOXIE
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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,842

Applicant(s)

POSANSKI, ULRICH

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/578,527.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 11 is objected to for minor informalities. The employment of parenthetical expression, e.g., (HLB value according to Griffin), in claims is considered informal.

Claim Rejections 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (U.S. Patent 5,576,025, AH) in view of Hauer et al. (U.S. Patent 5,342,625 AL), and in further view of Reggio et al. (US 4,379,169).

Akiyama et al. teaches a pharmaceutical composition of sparingly soluble drug that increase drug bioavailability of the drug. The carrier compositions work to increase residence time in the GI track. See the abstract. More specifically, the patented composition comprises oil, such as soybean oil, castor oil, rapeseed oil, etc. See column 5, lines 35-52, and optionally, a combination of two or more surfactants having different HLB values and optimized results may be obtained by varying the combination of surfactants with different HLB value. Column 5, lines 13-34. There is no particular limitation on the type of the drug. See, particularly, column 5 bridging column 6, line 3.

The primary reference does not teach expressly the employment of the particular combination of surfactants herein.

However, Hauer et al. teaches that cyclosporin is known for its low bioavailability due to its poor solubility. See, particularly, column 3, line 57 bridging column 4, line 44. Hauer also teach that the surfactants with various HLB values employed herein are known to be useful in cyclosporin composition. See, particularly, the hydrophilic surfactants and lipophilic surfactants in columns 9-12. Hauer expressly teach the employment of combination of hydrophilic surfactant and hydrophobic surfactant. See, column 9, lines 40-48 and examples 1.6-1.10 in column 26.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the particular combination of surfactants herein with a sparingly soluble pharmaceutical agent, such as cyclosporin in the composition of Akiyama

A person of ordinary skill in the art would have been motivated to employ cyclosporin and the surfactants herein in the composition of Akiyama because cyclosporins are known sparing soluble drug and the surfactants herein are known to be useful with sparingly soluble pharmaceutical agents, such as cyclosporin. Further, polyglycerol esters as lipophilic surfactants are old and well-known. See, e.g., Reggio et al. column 2, lines 2-9. The employment of those particular surfactants herein is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388), absent evidence to the contrary. Finally, preparing a pharmaceutical composition by simply mixing all the ingredients, which are

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obvious to one of ordinary skill, is within the skill of the artisan, and would be prima facie obvious.

4. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn (Biodegradable tenside, translation, AN) in view of Hauer et al. (U.S. Patent 5,342,625 AL) and in further view of Reggio et al. (US 4,379,169).

Hahn teaches how to select and make carrier composition for sparingly soluble pharmaceuticals based on several criteria. For instance, selection of carrier components can be based on shape and spatial characteristics of the pharmaceutical (section 3), HLB values (section 4), etc. See, also section 5, where Hahn teaches how to apply the preceding sections to arrive at suitable carrier components based on the characteristics of the pharmaceutical. The various characteristics of candidate tensides are listed in the table beginning on page 108. The tenside characteristics required to solubilize sparingly soluble pharmaceuticals are disclosed as being possessed by each of the 3 sets of ingredients claimed herein. The particular composition claimed herein wherein the sparingly soluble pharmaceuticals, such as cyclosporins, and the particular combination of surfactants is seen to be prima facie in view of Hauer et al., and in further view of Reggio et al. as discussed above. Finally, preparing a pharmaceutical composition by simply mixing all the ingredients, which are obvious to one of ordinary skill, is within the skill of the artisan, and would be prima facie obvious.

5. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauer et al. (U.S. Patent 5,342,625 AL).

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Hauer et al. teach a cyclosporin composition comprising cyclosporins, an oil, a hydrophilic surfactant (HLB>10) and lipophilic surfactant (HLB<10). See columns 9-12, particularly, column 9, lines 40-47 examples 1.6-1.10 on column 26-27.

Hauer et al. does not teach expressly the particular combination of surfactants herein. However, Hauer teaches sorbitan esters are similarly useful as lipophilic surfactants. See, particularly, column 12, lines 16-50. Further, polyglycerol esters as lipophilic surfactants are old and well-known. See, e.g., Reggio et al. column 2, lines 2-9.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to employ those particular combination of surfactants herein with a sparingly soluble pharmaceutical agent, such as cyclosporin because it is known in the art to employ a combination of lipophilic surfactant and hydrophilic surfactant for sparingly soluble pharmaceutical agents, such as cyclosporin. The employment of those particular surfactants herein is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388), absent evidence to the contrary. Finally, preparing a pharmaceutical composition by simply mixing all the ingredients, which are obvious to one of ordinary skill, is within the skill of the artisan, and would be prima facie obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to read 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

January 9, 2003